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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,437	01/09/2004	Bonita J.M. Ferrie	MM11130-1	8712

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DLA PIPER US LLP
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/754,437

Applicant(s)

FERRIE ET AL.

Examiner

Jeanine A. Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,12,13,23,25,26,36,38,48,80 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-9,12 and 13 is/are allowed.
- 6) ☒ Claim(s) 23,25,26,36,38,48,80 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed September 29, 2006. Currently, claims 1, 3-9, 12-13, 23, 25-26, 36, 38, 48, 80-81 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
3. This action contains new grounds of rejection.

Priority

4. This application claims priority to provisional application 60/439,188, filed January 10, 2003.

Drawings

5. The drawings are acceptable.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 36, 38, 48, 80-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

The claims are drawn to a method for genotyping a canis familiaris subject comprising contacting a nucleic acid sample from the canis familiaris subject with sets of probes or primers which are complementary to consensus regions between SEQ ID NO: 22 and 23 and wherein such first and second probes or primers flank non-consensus regions between SEQ ID NO: 22 and 23 and detecting different amplified products as correlative with a particular genotype.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

Genbank Accession Number AB080686 (3/6/02) is directed to a *canis familiaris* amelx gene for amelogenin, partial cds from a Labrador retriever.

Tachi et al. (J. of Reproduction and Development, Vol. 48, No. 6, 2002) teaches a partial amelogenin (AMELX) from an extinct wolf species, *Canis lupus hodophilax* Temminck, a Japanese wolf. Tachi teaches an alignment from the domestic dog (*Canis familiaris*; Labrador retriever) which illustrates differences between the canine amelogenin sequences (see Figure 2 of Tachi). Tachi teaches that the results strongly indicate that polymorphisms of the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. Tachi teaches that further molecular analysis of the intraspecific as well as the interspecific variations in the AMELX DNA will be needed to gain clear insight into the taxonomical and phylogenetic positions in the Japanese wolf.

Asano et al. (Am. Sc. J., Vol. 70, No. 10, pages J351-J362, October 1999) provides an alignment from wolf, dog, human, bovine, pig, mouse and rat amelogenin genes (Figure 6).

Guidance in the Specification and Working Examples

The specification specifically teaches that "additional regions of the canine amelogenin gene are likely to be identified from the complete canine amelogenin gene sequence that include nucleotide sequence differences between the copy of the gene on the X chromosome and on the Y chromosome (page 6, para 19). The specification also teaches that the sequences of the instant specification can be used to identify the

nucleotide sequence of the entire canine (e.g. dog) amelogenin X chromosome gene and Y chromosome gene (page 25, para 81).

The specification teaches that "all canine DNA samples analyzed in this example, were dog DNA samples" (page 27). The specification further teaches DNA was isolated from various male and female dogs (page 28, para 93). The specification fails to teach the number, the species or the similarity between the females analyzed, for example.

The specification teaches that Figure 5 provides a comparison of consensus sequences of canine X (SEQ ID NO: 22) and Y (SEQ ID NO: 23) partial amelogenin sequences. The shaded sequences and gaps indicate differences between the canine AMELX and AMELY sequences.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses an alignment of consensus sequences. The specification fails to provide whether each of the identified differences between the two consensus sequences is X or Y specific.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied

The claims are broadly drawn to any genotype. The instant specification has only exemplified an association between SEQ ID NO: 22 and 23 with gender. There is no illustration of any association between these two sequences and any other genotype, including dog breed, cancer, arthritis or kidney failure, for example. It would require

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additional undue experimentation to analyze the gaps of SEQ ID NO: 22 and 23 to associate the different products with any genotype. While the skilled artisan could perform such experimentation, the results of the experimentation are unpredictable and undue in view of the art and instant specification.

Each of these described issues would require much inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the specification fails to provide enough guidance or teachings to practice the scope of the claims as broadly as claimed. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized differences in sequences and species, for example. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25-23, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 23, 25-26, 36, 38, 48 and 80-81 are indefinite over the recitation "the complementary regions" in line 5 of Claim 23. "The complementary regions" lacks proper antecedent basis. The claim does not provide for any complementary regions. Appropriate correction is required.

Further, the claims are directed to determining the presence of homologous canine amelogenin sequences. In biology, two or more structures are said to be **homologous** if they are alike because of shared ancestry. It is unclear how the binding of two primers in a consensus region of SEQ ID NO: 22 or 23 would be indicative of homologous sequences. This would imply that two different sequences are present which is not necessarily the case in the event of a female. An X canine amelogenin sequence would not be homologous to another X canine amelogenin sequence. Thus, the use of homologous is unclear and indefinite.

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B) Claims 36, 38, 48 and 80-81 are indefinite over the recitation "the first set of probes or primers" in line 3 of Claim 36. The first set of probes lacks proper antecedent basis. The claims were amended to be drawn solely to primers. Thus "the first set of probes or primers" lacks proper antecedent basis.


Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.


Jeanine Goldberg
Primary Examiner
December 22, 2006